	Application No.	Applicant(s)
Notice of Allowability	10/813,421	HARTER ET AL.
	Examiner	**Art Unit**	
	Tran Nguyen	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *BPAI Decision issued 04/23/2009*.

2. ☒ The allowed claim(s) is/are *1 and 3-34*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) ☐ All   b) ☐ Some*   c) ☐ None   of the:

        1. ☐ Certified copies of the priority documents have been received.

        2. ☐ Certified copies of the priority documents have been received in Application No. _____ .

        3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the

           International Bureau (PCT Rule 17.2(a)).

    * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

    (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

        1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____ .

    (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of

        Paper No./Mail Date _____ .

    Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)
1. ☒ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO/SB/08),
    Paper No./Mail Date _____

4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☒ Interview Summary (PTO-413),
    Paper No./Mail Date *08/03/2009* .

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____ .

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626

DETAILED ACTION

Notice to Applicant

This communication is in response to the BPAI decision issued 04/23/2009.

Pending claim(s): 1, 3-34. New claim(s): 34.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes

and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be

submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview

with Robert J. Harter on 07/31/2009.

The application has been amended as follows:

1. (Amended) A method of using a computer and a computer display for

identifying a suspect influencing agent that may be causing a reaction in an individual,

wherein the suspect influencing agent is one of a plurality of possible influencing

agents, the method comprising:

displaying the plurality of possible influencing agents on the computer display;

displaying the reaction on the computer display;

for a first period, selecting a first plurality of influencing agents from the plurality

of possible influencing agents, wherein the individual was exposed to the first plurality of

influencing agents during the first period, wherein the step of selecting the first plurality

of influencing agents is via the computer;

for a second period following the first period, selecting a second plurality of

influencing agents from the plurality of possible influencing agents, wherein the

individual was exposed to the second plurality of influencing agents during the second

period, wherein the step of selecting the second plurality of influencing agents is via the

computer;

selecting, via the computer, the reaction that the individual experienced during at

least one of the first period, the second period, and a third period, wherein the third

period follows the second period;

computing, with the computer, a plurality of correlations corresponding to the

plurality of possible influencing agents as each of the plurality of possible influencing

agents relate to the reaction;

and based on the plurality of correlations, determining, with the computer, and

displaying the suspect influencing agent.

32. (Amended) A method of using a computer and a computer display for

identifying a suspect influencing agent that may be causing a reaction in an individual,

wherein the suspect influencing agent is one of a plurality of possible influencing

agents, the method comprising:

entering into the computer the plurality of possible influencing agents;

displaying the plurality of possible influencing agents on the computer display;

entering the reaction into the computer;

displaying the reaction on the computer display;

for a first period, selecting, with the computer, a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse- clicking on at least some of the plurality of possible influencing agents;

for a second period following the first period, selecting, with the computer, a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of influencing agents;

selecting, via the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period;

computing, with the computer, a plurality of correlations corresponding to the plurality of possible influencing agents as each of the plurality of possible influencing agents relate to the reaction;

adding, with the computer, after the first period, an additional influencing agent to the plurality of possible influencing agents;

and based on the plurality of correlations, determining, with the computer, and displaying, with the computer, the suspect influencing agent.

33. (Amended) A method of using a computer and a computer display for identifying a suspect influencing agent that may be causing a reaction in an individual, the method comprising:

entering into the computer a plurality of possible influencing agents, wherein the plurality of possible influencing agents includes the suspect influencing agent, and wherein at least one of the plurality of possible influencing agents is a food;

displaying the plurality of possible influencing agents on the computer display;

entering the reaction into the computer;

displaying the reaction on the computer display;

for a first period, selecting, with the computer, a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents from the plurality of possible influencing agents is performed by mouse- clicking on at least some of the plurality of possible influencing agents;

for a second period following the first period, selecting, with the computer, a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing

agents from the plurality of possible influencing agents is performed by mouse-clicking on at least some of the plurality of possible influencing agents;

selecting, with the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period, wherein the step of selecting the reaction is performed by mouse-clicking on the reaction;

computing, with the computer, a plurality of correlations corresponding to the plurality of possible influencing agents, wherein the plurality of correlations reflect the likelihood that the plurality of possible influencing agents will cause a future reaction;

adding, with the computer, after the first period, an additional influencing agent to the plurality of possible influencing agents;

sorting, with the computer, the plurality of possible influencing agents based on the plurality of correlations;

plotting a graph of the suspect influencing agent and the reaction versus time, and displaying the graph on the computer display to help illustrate how well the suspect influencing agent and the reaction correlate;

assigning a magnitude value to the reaction;

and displaying the magnitude value on the computer display.

34. (New) A method of identifying a suspect influencing agent, comprising:

storing a plurality of possible influencing agents into a computer;

storing a plurality of reactions into the computer;

selecting, with the computer, a plurality of possible influencing agents from the

stored possible influencing agent, wherein an individual was exposed to the selected

possible influencing agents;

selecting, with the computer, a reaction from the plurality of stored reactions,

wherein the individual experienced the selected reaction after exposure to the selected

possible influencing agents;

computing, with the computer, a correlation between each one of said selected

possible influencing agents and the selected reaction;

determining, with the computer, the possible influencing agent having the highest

computed correlation from the plurality of computed correlations;

displaying the determined possible influencing agent having the highest

computed correlation as the suspect influencing agent suspected of causing the

reaction in the individual.

Statutory Subject Matter - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the
conditions and requirements of this title.

As per claim 1, based on Supreme Court precedent and recent Federal Circuit

decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to

a machine or (2) transform underlying subject matter (such as an article or materials) to

a different state or thing. *In re Bilski* et al, 88 USPQ 2d 1385 CAFC (2008); *Diamond v.*

Diehr, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978);

Gottschalk v. Benson, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88

(1876).

An example of a method claim that would not qualify as a statutory process

would be a claim that recited purely mental steps. Thus, to qualify as a statutory

process, the claim should positively recite the particular machine to which it is tied, for

example by identifying the apparatus that accomplishes the method steps, or positively

recite the subject matter that is being transformed, for example by identifying the

material that is being changed to a different state.

In particular, all method steps of claim 1 are positively recited as being performed

by a "computer". Therefore, all steps of method claim 1 require the particulars of a

statutory machine.

As such, claim 1 is found to be directed towards statutory subject matter.

All claims dependent thereon, namely claims 3-31, are also found to be directed

towards statutory subject matter for at least the same rationale as applied to claim 1

above, and incorporated herein.

As per claims 32-34, these claims are also found to be directed statutory subject

matter for at least the same rationale applied to claim 1 above, and incorporated herein.

Written Description - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MPEP 2163(I)(B) reads as follows:

"While there is no *in haec verba* requirement, **newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure**".

MPEP 2163.02 reads as follows:

"An applicant shows possession of the claimed invention by **describing the claimed invention with all of its limitations** using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines,* Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997)".

As per claim 1, this claim recites:

"displaying the plurality of possible influencing agents on the computer display;

displaying the reaction on the computer display;

for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents is via the computer;

for a second period following the first period, selecting a second plurality of

influencing agents from the plurality of possible influencing agents, wherein the

individual was exposed to the second plurality of influencing agents during the second

period, wherein the step of selecting the second plurality of influencing agents is via the

computer;

selecting, via the computer, the reaction that the individual experienced during at

least one of the first period, the second period, and a third period, wherein the third

period follows the second period;

computing, with the computer, a plurality of correlations corresponding to the

plurality of possible influencing agents as each of the plurality of possible influencing

agents relate to the reaction;

and based on the plurality of correlations, determining, with the computer, and

displaying the suspect influencing agent."

Figure 3, 5 of the specification as originally filed on 03/30/2004 disclose:
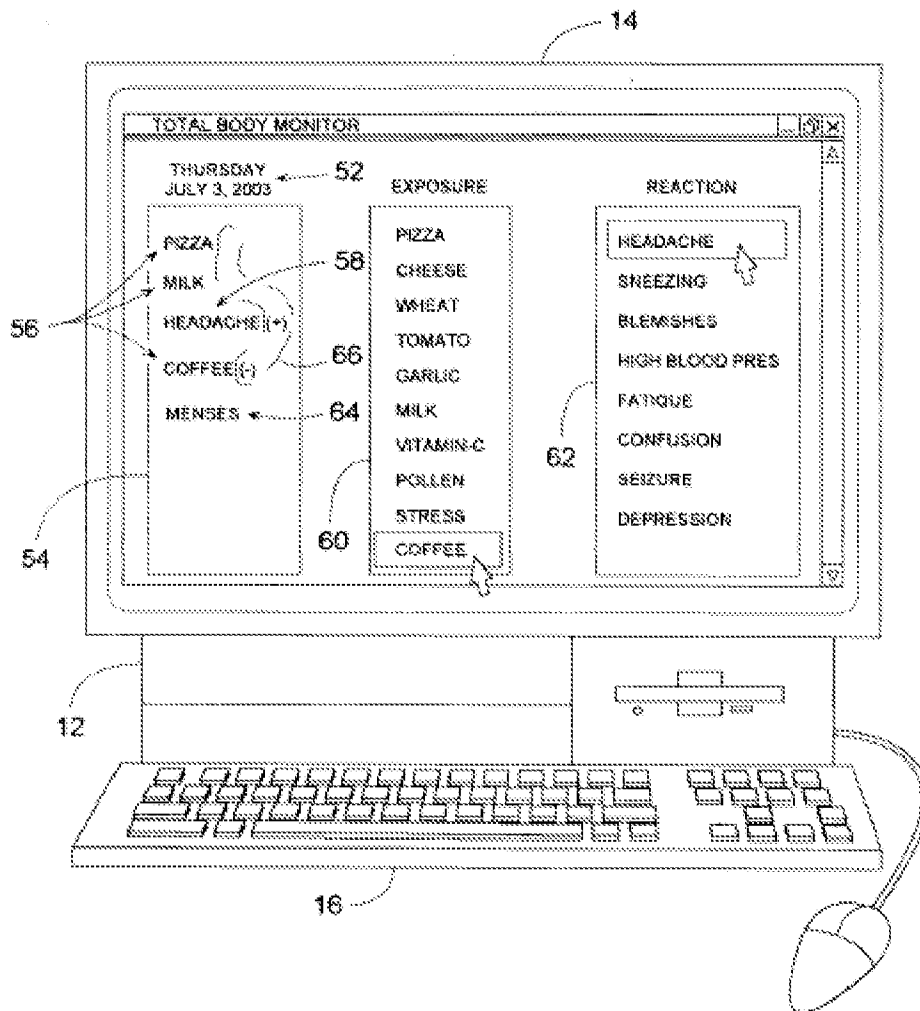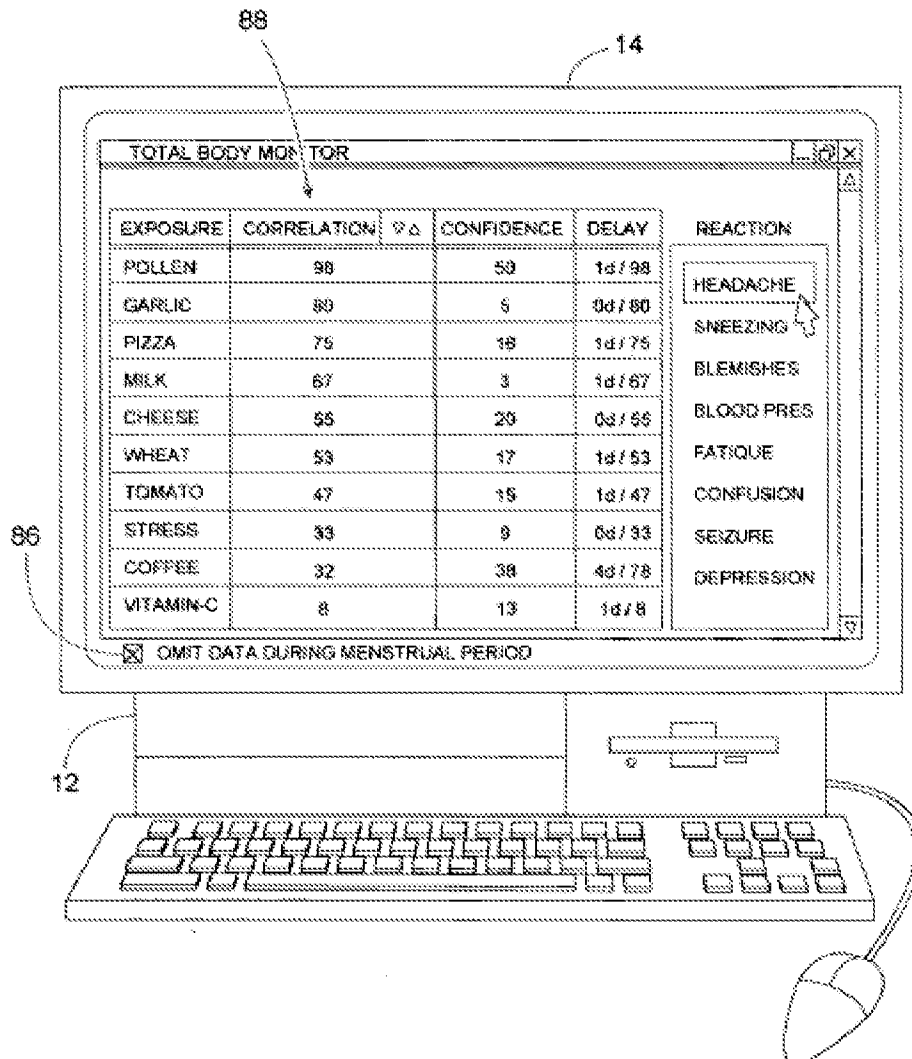
FIG. 3

FIG. 5

EXPOSURE	CORRELATION ▽△	CONFIDENCE	DELAY	REACTION
POLLEN	98	50	1d / 98	HEADACHE
GARLIC	80	5	0d / 80	SNEEZING
PIZZA	75	18	1d / 75	BLEMISHES
MILK	67	3	1d / 67	BLOOD PRES
CHEESE	55	20	0d / 55	FATIGUE
WHEAT	53	17	1d / 53	CONFUSION
TOMATO	47	19	1d / 47	SEIZURE
STRESS	33	9	0d / 33	DEPRESSION
COFFEE	32	38	4d / 78	
VITAMIN-C	8	13	1d / 8	

☒ OMIT DATA DURING MENSTRUAL PERIOD

The specification as originally filed provides support for the features of allowing

the user to select possible allergens for a plurality of time periods (Figure 3), selecting

the reaction (Figure 3), and displaying the allergen most likely to have caused the

reaction (Figure 5).

Support for all claims dependent thereon, namely claims 3-31, as well as independent claims 32-34 may also be found in the specification as originally filed.

Allowable Subject Matter

Claims 1, 3-34 are allowed.

The following is an examiner's statement of reasons for allowance:

As per claim 1, the primary reason for allowance is the inclusion of the following limitations not found in the best available prior art:

" for a first period, selecting a first plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the first plurality of influencing agents during the first period, wherein the step of selecting the first plurality of influencing agents is via the computer;

for a second period following the first period, selecting a second plurality of influencing agents from the plurality of possible influencing agents, wherein the individual was exposed to the second plurality of influencing agents during the second period, wherein the step of selecting the second plurality of influencing agents is via the computer;

selecting, via the computer, the reaction that the individual experienced during at least one of the first period, the second period, and a third period, wherein the third period follows the second period;

computing, with the computer, a plurality of correlations corresponding to the

plurality of possible influencing agents as each of the plurality of possible influencing

agents relate to the reaction;"

The closest available prior art are as follows:

Buchanan (20060090215) teaches (page 9-10):

[0102] Skin Testing

[0103] There are two general approaches to allergy skin testing—the prick and the injection methods. In the prick method, a drop of extract is introduced using a small sharp instrument, causing a small break in the skin. With the injection method, a drop of allergen extract is injected into the top layer of the skin, raising a small bubble on its surface. Both of these tests are simple and inexpensive. The prick method has advantages in that it's safe, causes very little discomfort to the patient and allows medical personnel to test many allergens in one session.

[0104] In either method, the allergy extract causes a reaction in the skin in about 20 minutes. A negative reaction shows no change, while a positive reaction causes a small red welt to develop. The size of the welt is measured to determine the strength of the reaction.

[0105] The skin test may be performed upon humans or animals that are allergic to the particular allergen. In some cases, an alternative animal model may be used. For example, atopic dogs may be used as an animal model for human allergies.

[0106] For the skin prick test, a tiny amount of allergen is lightly pricked into the superficial skin. If a patient has an allergy, the specific allergen that the patient is allergic to will cause a chain reaction to begin in the patient's body. The spot where the allergen entered the skin will swell and itch a bit, forming a hive smaller than a quarter. The test results are generally available within 15 minutes of testing and the small hives where the test was done go away within 30 minutes.

[0107] The intradermal test involves injecting a tiny amount of allergen under the skin, usually on the upper arms or the abdomen of dogs.

[0108] Oral Challenge Tests

[0109] Challenge tests involve having a patient inhale or swallow a very small amount of the suspected allergen, such as milk or an antibiotic. If there is no reaction, the dose may be slowly increased. Since challenge tests may induce severe allergic reactions, they are only done when absolutely necessary, and must be closely supervised by an allergist.

[0110]   Blood Tests

[0111]   A patient's blood may be analyzed to determine
sensitivity to various antigens using various immunoassay
techniques. These methods include, but are not limited to,
radioallergosorbent (RAST) inhibition tests, IgE immunob-
lot enzyme linked immunosorbent assays (ELISA), radio-
immunoassays (RIA), "sandwich" immunoradiometric
assays (IRMA), and enzyme-labeled immunodot assays as
described in *Antibody Techniques*, V. Malik and E. Ullehoj
Editors, 1994 Academic Press.

Although Buchanan teaches known technique in the art to test for an allergy,

Buchanan does not teach entering possible allergens, to which the patient was

exposed, into a computer, entering the patient's allergic reaction into the computer, and

using the computer to determine which of the possible allergen is most likely to have

caused the reaction.

Berkow (The Merck Manual of Diagnosis and Therapy, copy mailed 03/20/2008)

teaches known techniques to diagnose food allergy (page 328-330).

Nevertheless, Berkow does not teach entering possible allergens, to which the

patient was exposed, into a computer, entering the patient's allergic reaction into the

computer, and using the computer to determine which of the possible allergen is most

likely to have caused the reaction.

Evans (A Computer Assisted Management Program for Antibiotics and Other

Antiinfective Agents, copy mailed 03/20/2008) teaches using a computer to identify drug

interactions (page 233 Figure 1).

Nevertheless, Evans does not remedy the deficiencies of Buchanan and Berkow as discussed above.

In particular, Evans does not teach entering possible allergens, to which the patient was exposed, into a computer, entering the patient's allergic reaction into the computer, and using the computer to determine which of the possible allergen is most likely to have caused the reaction.

Additionally, the BAPI decision rendered on 04/23/2009 reads as follows (page 9-10):

> We agree with the Appellants. We first construe the meaning of the
> word "correlation" as used by the Appellants in the claims. We determine
> the scope of the claims in patent applications "not solely on the basis of the
> claim language, but upon giving claims their broadest reasonable
> construction 'in light of the specification as it would be interpreted by one of
> ordinary skill in the art.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316
> (Fed. Cir. 2005) (*en banc*) (*quoting In re Am. Acad. of Sci. Tech. Ctr.*, 367
> F.3d 1359, 1364 (Fed. Cir. 2004)). The Specification at page 7, lines 13-15
> defines "correlation" as "a value or symbol that provides at least some
> indication of how closely the occurrence of one item relates to another" and
> we use this definition in defining the term in the claims.
>
> Claim 1 requires "computing a plurality of correlations corresponding
> to the plurality of possible influencing agents as each of the plurality of
> possible influencing agents relate to the reaction." Berkow discloses that in
> the assessment of etiologic factors that confirmation is best accomplished by
> an allergy evaluation that includes skin testing (FF1). Berkow discloses that

the clinical significance of the (test) results are correlated to the symptoms and related to environmental exposures (FF3). Berkow fails to specifically disclose correlating a plurality of possible influencing agents as each of the influencing agents relate to the reaction (FF4). Further, Berkow does not disclose "based on the plurality of correlations, determining and displaying the suspect influencing agent" (FF5) as required in claim 1. While Berkow does disclose the use of an elimination diet, such a test provides for an elimination of foods as opposed to a "correlation" or a value or symbol that provides at least some indication of how closely the occurrence of one influencing agent relates to a reaction as described in the Specification. Further, the citation in Berkow relating to elimination diets (page 329) has not been shown to relate to Berkow's citation on allergy skin testing (page 650) which is from an entirely different section of the referenced Merck Manual. As Berkow fails to disclose or suggest the above identified claim limitations we will not sustain the rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over Berkow and Evans.

In this case, the BPAI has determined that Berkow, in combination with Evans, fails to teach calculating a plurality of "correlations".

As such, even though Berkow teaches ruling out a particular allergen or identifying a particular allergen as the cause of the reaction, the BPAI has found that this elimination technique does not amount to calculating a "correlation" as defined by Applicant.

Therefore, claim 1 is also allowed for this reason.

The closest foreign patent art also belongs to Buchanan (WO30686052). Similar teachings as discussed above with respect to Buchanan '215 also applies to Buchanan '052.

All claims dependent thereon, namely claims 3-31, are also allowed for at least the same rationale as applied to claim 1 above, and incorporated herein.

As per claims 32-34, these claims are allowed for at least the same rationale as applied to claim 1 above, and incorporated herein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3626
08/04/2009

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626